SEP 2 4 2003

K032402

Convaid
PRODUCTS INC

P.O. Box 4209 • Palos Verces, CA 90274 USA
Toll Free (888) CONVAID (266-8243) or (800) 552-1020
(310) 539-6814 • Fax (310) 539-9570

Convaid Product Inc.
Model: RODEO Manual Wheelchair

510(k) Summary
of
Safety and Efficacy

A. General Information

1.	Submitter Name:	Convaid Products Inc.
2.	Address:	2830 California St. Torrance CA, 90503
3.	Telephone: Fax:	310-618-0111 310-618-2166
4.	Contact Person:	Donald Griggs Quality Assurance Manager
5.	Registration Number:	2022883
6.	Date Prepared:	

B. Device

1.	Device Trade Name:	Rodeo – Mobile Positioning System
2.	Common/Generic Name:	Wheelchair-folding tilt in space
3.	Device Classification Name:	Mechanical Wheelchair
4.	Registration Number:	222022883
5.	Product Code:	IOR
6.	Device Classification	Class 1
7.	Regulatory Number:	980.3850

C. Identification of Legally Marketed Devices

1.	Manufacture Name:	Sunrise Medical
2.	Name:	Quickie TSR
3.	K Number:	K952641
4.	Date Cleared:	07/06/1995

1.	Manufacture Name:	Sunrise Medical
2.	Name:	Quickie Zippie Series
3.	K Number:	K973673
4.	Date Cleared:	11/20/1997

D. Intended Use

The Rodeo manual wheelchairs are a tilt in space mobile positioning system for everyday use on flat terrain. They are available in a range of sizes to accommodate a particular fit to the user. It is an attendant propelled device, its' intended function and use is to proved mobility to persons that are limited to a sitting position.

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E. Description of the device

The Rodeo model is constructed of the same materials and contains the same typical components found on most manual wheelchairs. The frame consists primarily of powder coated round tubular steel from 5/8" to 1" diameter, that is welded, bolted and riveted. With 6" front wheels attached to pivoting casters for steering and turning, and 8" wheels in the rear. The product is a lightweight folding or non-rigid type wheelchair, which is designed for everyday indoor or outdoor use on firm terrain. Also available with a transit option for use in approved transport vehicles. The Rodeo offers its users a 10°-45° of adjustable tilt and 90°-105° of seat to back angle adjustment and comes with a standard sling type back and seat, the upholstery fabric meets the California Technical Bulletin CAL 117 Standard for flame retardancy. Adjustable seat depth, footplate and height of push handle.

F. Technological Characteristics Summary

The Rodeo wheelchair is substantially equivalent to
Sunrise Medicals **Quickie Model "Zippie TS Folding Model".**
The Sunrise Medical "Quickie TSR" was cleared 07/06/1995 on K952641.
Also reference Sunrise Medicals Quickie/Zippie Series cleared 11/20/1997 on K973673.
Sunrise Medicals "Zippie TS folding frame" and Convaid's "Rodeo" wheel chairs are a tilt-in-space mobility system, manual wheelchair for everyday use, both frames are built using tubular steel that is welded, bolted and riveted. They are a folding non-rigid wheelchair and use a compression folding system that allow for easy transport and storage. The Convaid Rodeo is an attendant propelled manual design and does not come with the Zippie TS option to be self-propelled.
Adjustable push handle height, and adjustable back angle, adjustable seat depths. Similar seat widths and weights.

G: Comparison of device characteristics to predicate

This device (Convaid Rodeo) has similar characteristics, construction and technology as the predicate device manufactured by Sunrise Medical the Zeppie TS folding model.

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H: Target Population:

This device is indicated for individuals with the specific medical conditions Listed, but the indications are not necessarily limited to such conditions:

- Amputee;
- Arthritis;
- Arthrogriposis;
- Cerebral Palsy;
- Geriatric conditions;
- Head injury or trauma;
- Hemiplegics;
- Multiple Sclerosis;
- Muscular Dystrophy;
- Paraplegic;
- Polio;
- Quadriplegic;
- Spina Bifida;
- StokeJCVA;
- Tetraplegic; and
- Other immobilizing or debilitating conditions, including spinal cord injuries and Other lower and upper extremity paralysis

I: Non-Clinical Testing

Convaid's Rodeo manual wheelchairs meet the applicable performance requirements as specified in ANSI/RESNA WC vol. 1 or ISO 7176 Wheelchair Standards as indicated in section 2 page 2-3. Including ANSI/RESNA W/C 19 Wheelchair use as seating in motor vehicles.

J: Safety:

The Convaid Rodeo Wheelchair Series is substantially equivalent to the predicated device listed in the 510(k); the technology and construction of the Rodeo Wheelchair series does not raise any new issues of safety and effectiveness.

K: Conclusion:

The Rodeo Wheelchair series shares performance features and technology with a number of devices already legally marketed within the United States. Therefore, the Rodeo Series wheelchairs are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 2003

Mr. Donald Griggs
Quality Assurance Manager
Convaid Products, Inc.
2830 California Street
Torrance, California 90503

Re: K032402
Trade/Device Name: Rodeo Models RD12, RD14, RD16
Rodeo Transit Models RD12T, RD14T and RD16T
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: I
Product Code: IOR
Dated: July 28, 2003
Received: August 4, 2003

Dear: Mr. Griggs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Voluntary performance standard:
Non-Clinical Testing of Convaid's Rodeo manual wheelchairs meet the applicable performance requirements as specified in the following ANSI/RESNA or ISO Wheelchair Standards.

ANSI/RESNA W/C 5	Determination of Overall Dimensions, Mass and Turning Space
ISO 7179- 8-10	Fatigue Strength Test
ANSI/RESNA W/C 15	Documentation and Labeling
ANSI/RESNA W/C 16	Flammability
ANSI/RESNA W/C 19	Wheelchair use as seating in motor vehicles

Statement of Indication of use

Convaid's Rodeo manual wheelchairs and Sunrise Medical Zippie TS are a tilt in space mobile positioning system for everyday indoor and outdoor use on flat firm terrain. They are available in a range of sizes to accommodate a particular fit to the user. The Convaid Rodeo is a attendant propelled device, its' intended function and use is to proved mobility to persons that are limited to a sitting position. It has a variety of options to control or support the users specific needs.

Target Population:
This device is indicated for individuals with the specific medical conditions Listed, but the indications are not necessarily limited to such conditions:

- Amputee;
- Arthritis;
- Arthrogriposis;
- Cerebral Palsy;
- Geriatric conditions;
- Head injury or trauma;
- Hemiplegics;
- Multiple Sclerosis;
- Muscular Dystrophy;
- Paraplegic;
- Polio;
- Quadriplegic;
- Spina Bifida;
- StokeJCVA;
- Tetraplegic; and
- Other immobilizing or debilitating conditions, including spinal cord injuries and Other lower and upper extremity paralysis

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K032402